TAB 8

or has an implied duty to cease using.
Id. at 27-4.

The SB/Biken agreement specifically addressed SB's rights after expiration:

> Upon expiration of this Agreement pursuant to the provisions of Section 12.01 hereof neither party shall be relieved of any rights and obligations which have accrued prior to expiration including those listed in Section 12.06, paragraphs (a)-(c) hereof, and SK & F shall continue to be entitled to exercise the rights and licenses granted herein without further payments to the Foundation.

(PTX552, § 12.07) (emphasis added). As noted, in relevant part the license "granted herein" was "a nonexclusive right and license to use the ... Know-How to make, have made, use and sell the vaccine in the Contract Territory." Accordingly, after expiration of the agreement SB could continue royalty-free to use the Know-How "in the Contract Territory," but not otherwise.

The licensing agreement imposed on SB an affirmative obligation to keep the Know-How confidential (PTX552, § 8.01) but allowed disclosures to regulatory agencies (which keep such information confidential) in connection with seeking government approval:

> 8.04 These obligations of non-disclosure shall not apply to any information which SK & F may be required to disclose in order to obtain essential or desirable authorizations or rights relating to the Vaccines from governmental authorities within the Contract Territory or as otherwise required by law.

***24** (PTX552, § 8.04). Thus, SB was only entitled to disclose Biken Know-How to "governmental authorities within the Contract Territory," and was not entitled to do so in the United States or Canada.

SB's assertion that Section 8.01 entitles SB to disclose Biken's Know-How after 1997 is incorrect for two reasons. First, SB's claim as to a 1997 "disclosure" date rests on the assertion that, because the agreement ceased to be effective in some countries in 1992 under Section 12.01, the obligations of Section 8.01 similarly ceased to be effective and SB then became free to disclose the Know-How in those countries beginning five years later. However, unlike Section 12.01, Section 8.01 does not refer to being "effective" on a country-by-country basis, but speaks only of "the term of this Agreement and for five (5) years thereafter." The term of the agreement necessarily means when the agreement expired under Article 12, which SB concedes was March 1995 (TX2640). It would make no sense to allow disclosure of confidential information on a country-by-country basis. Thus, even assuming Section 8.01 at some time allows disclosure by SB of Biken's confidential information, the earliest such disclosure could occur is March of 2000, five years after the agreement expired in 1995. The fact that SB has not done what it claims it is entitled to do--disclose all of Biken's Know-How beginning in 1997--is further evidence that SB does not actually believe it has the right it claims.

Second, even in the year 2000, Section 8.01 does not give SB the right to disclose Biken Know-How. The affirmative obligation in Section 8.01 "to take every reasonable precaution" to keep information confidential ends at that time. However, that does not mean that SB is thereafter free to disclose Biken's Know-How--nothing in Section 8.01 or elsewhere in the agreement gives SB such a right.

Given that SB had a continuing right, under Section 4.01, to obtain technical information "during the effective period of this Agreement," SB's construction--under which it could acquire Biken's process information as late as 1995 and disclose it shortly thereafter--is unreasonable. A five-year limit on SB's affirmative obligation to take precautions is reasonable. After five years, any Biken Know-How incorporated in SB's process would continue to be protected in the way SB protects its process information. And any Biken Know-How which SB acquired but chose not to use in all likelihood would have been destroyed or stored in old records from which disclosure was unlikely.

Every agreement contains an implied duty to act in good faith, Greco v Columbia/HCA Healthcare Corp., Del. Ch., C.A. No. 16801, 1999 Del. Ch LEXIS--24 at *30, Strine, V.C. (Feb. 11, 1999), which also precludes any publication by SB of Biken's Know-How. Even under SB's interpretation of its "disclosure" right, which would allow SB to disclose and use the Biken Know-How without limit beginning in either 1997 or 2000, it still obtained an improper and significant head start by the commencement of United States approval activities

in 1993.

F. Merck is Entitled to an Injunction

***25** This Court is authorized under 6 Del. C. § 2002(a) to grant an injunction to remedy misappropriation of a trade secret. An injunction is meant " 'to protect the secrecy of the misappropriated information, eliminate the unfair advantage obtained by the wrongdoer and reinforce the public policy of commercial morality." ' Miles Inc. v. Cookson America, Inc., 1994 WL 676761 at *20 (Del. Ch. Nov. 15, 1994) (quoting General Elec. Co. v. Sung, 843 F.Supp. 776, 778 (D.Mass.1994)). Thus, the length of the injunction is based on the time advantage obtained by the defendant as a result of its misappropriation: "An injunction should last for as long as is necessary, but no longer than is necessary, to eliminate the commercial advantage or 'lead time' with respect to good faith competitors that a person has obtained through misappropriation." Uniform Trade Secrets Act (U.L.A.) § 2 Comments at 450 (1979); see also Miles, 1994 WL 676761, at *20; K-2 Ski Co. v. Head Ski Co., 506 F.2d 471, 474 (9th Cir.1974).

Courts have consistently recognized that the development of a commercial process takes many years and have not hesitated to impose lengthy injunctions where the defendant has obtained a significant gain in the time required to develop a process. See, e.g., Miles (three year production injunction as to certain pigments and two year injunction as to others); General Elec. Co. v. Sung, (seven year production injunction); Televation Telecomms. Sys. Inc. v. Saidon, 522 N.E. 2nd 1359, 1366 (Ill.App.1988) (three year production injunction). As the Saidon Court noted, "The appropriate injunction period should be the time required to legally produce a competing product, not merely the disputed portions of the product." Id. at 1367 (citations omitted).

The record establishes that SB obtained a time advantage of three to five years as a result of its misappropriation (Tr. 1346-51). Development of a commercial process for the production of varicella vaccine is an especially long undertaking, as shown by the experience of the three companies that have done it.

The substantial time required to develop such a commercial process is a function of the many variables that must be considered in any vaccine production process (Tr. 52-64), compounded by the particular difficulties associated with varicella. Those difficulties include the small amount of virus that can be produced relative to other viruses and the intracellular and fragile nature of varicella (Tr. 41-44, 108-18, 132-35). Moreover, there is substantial time involved in conducting, obtaining the results of, and successfully repeating experiments (Tr. 924-25; Didelez dep. 720-21; Thysman dep. 221).

In addition, the production process for varicella vaccine is nonlinear, so that a change in one step may have unexpected consequences elsewhere (Tr. 127-28, 1021-22; Didelez dep. 230, 232). Thus, a company may think that it is almost to the point of having a successful process but in fact what appears to be just a little way left to go is a major problem. For example, SB thought it was almost done with its development in September 1989 when Didelez proposed his most plausible scheme, but in fact, the scheme did not work at all. The substantial savings of time acknowledged in SB's trip report following the Biken visit also confirms the time advantage it obtained (PTX124). SB has not provided significant counter-arguments to the three to five year estimate, merely arguing that "SB did not save three-five minutes based on the visit to Japan--much less the three-five years advocated by Dr. Wang." I think the evidence, overwhelmingly, is to the contrary. As a result, I will enter an injunction against SB for three years.

***26** Because SB has not yet obtained approval to market its vaccine in either the United States or Canada and the actual approval date is uncertain, the injunction must run from the date approval is obtained in order to deprive SB of the time advantage it has improperly gained. Considering that SB saved at least three years in the development of its commercial process, Merck is entitled to an injunction against SB from marketing its varicella vaccine in the United States or Canada for a period of three years from the date it receives approval to market its vaccine in those countries.

III.FACTS SURROUNDING SB'S COUNTERCLAIMS AND AFFIRMATIVE DEFENSES [FN11]

FN11. Some of these facts may be repetitive of

> those in the fact section concerning Merck's claim, but because the reader last encountered those facts 60 or so pages ago, I feel compelled to repeat them.

A. The Option Agreement

On June 1, 1975, Biken and SB entered into an Option Agreement, under which SB would evaluate the Oka strain (PTX306). The Option Period was two years (PTX306, Art. 3), or until June 1, 1977. SB initially had asked for a three-year Option Period (PTX310) and then a thirty-month period (PTX305), but Biken had been unwilling to agree to a period longer than two years. Biken's insistence on only a two-year Option Period indicates the importance to Biken of SB's successful development of a vaccine and the subsequent agreement to a license on terms acceptable to Biken.

Under the agreement, SB had to notify Biken whether it desired a license at least three months prior to the expiration of the Option Period (PTX306, Art. 4). If SB did not want a license or if a licensing agreement was not reached within six months after SB notified Biken that it desired a license, the agreement terminated (id. at PTX306). Thus, the agreement gave SB twenty-one months, until March 1, 1977, in which to evaluate the Strain and to notify Biken if it wanted a license. If SB did want a license, an agreement had to be finalized by September 1, 1977. SB was not required to take a license under the Option Agreement. Likewise, Biken was not required to grant a license, except on terms acceptable to it.

Article 3 of the Agreement defined the Option Period as "twenty-four (24) months from the date of this Agreement," and several obligations of the Agreement were tied expressly to the Option Period (as opposed to the term of the agreement). Article 1, paragraph 2 of the Option Agreement imposed the following limit on Biken:

> The Foundation agrees not to give such option or any license for manufacture, sale or use of a varicella vaccine made from their Strain to any third party during the Option Period as specified in Article 3 and for three months thereafter.

While the Option Agreement limited Biken's ability to actually grant a license to a third party during the defined period, the Option Agreement imposed no limit on Biken's ability to meet or to negotiate at any time with third parties who were interested in a license.

Article 5, paragraphs 1 through 4 of the Option Agreement imposed confidentiality obligations on the parties, as follows:

> 1. [SB] agrees that the Strains as well as information and data as furnished by the Foundation hereunder shall be kept strictly secret and confidential with the best possible care and safeguards during the term of this Agreement, as well as a period of five years thereafter, with respect to any third party unless it has obtained the prior consent of the Foundation.
>
> ***27** 2. [SB] further agrees that its officers or employees or any third party including its affiliate companies who will be given access to the Strain and information and data furnished hereunder for the purposes agreed to between the parties shall be under the same obligations as those of SB hereunder.
>
> 3. In case [SB], its officers or employees or any other party furnished by [SB] with the Strain and information and data with a prior written or implied consent of the Foundation shall have committed a substantial default, non-fulfillment or breach of the covenants or provisions herein contained, [SB] shall be responsible for any and all damages caused to the Foundation due to such default, non-fulfillment or breach.
>
> 4. The Foundation also agrees during the Option period and during the term of any license agreement executed pursuant thereto not to disclose the Strain and information and data relating thereto, including any data, strains, or information provided by [SB], to any third party except to enable the Foundation to conduct research testing in the field, to publish or release the same to scientific and/or academic institutions, and to deposit a limited quantity of its own Strain to ATCC, U.S.A., or other accredited depositories for the purpose of facilitating the Foundation's patent applications.

Biken's obligations under Article 5, paragraph 4 were limited expressly to the duration of "the Option Period" and "the term of any license agreement executed pursuant thereto." Thus, if a license agreement was not reached by the end of the Option Period, those obligations lapsed. In addition, under the express terms of Article 5, paragraphs 2 and 3, SB was responsible for any disclosures of confidential information made by third parties to whom SB had given the Oka strain or information

related thereto.

B. June 1975 to May 1977: SB Encounters Initial Problems Leading to an Extension of the Option Period

1. SB's Problems

Shortly after signing the Option Agreement, SB received a sample of the Oka strain from Biken. Both that sample and a subsequent sample were found to have mycoplasma contaminants (TX2188). SB encountered additional problems as well; there was a delay of several months because SB could not use the lab where it prepared batches of diploid cells (PTX315). In addition, there were technical difficulties with the Oka strain (PTX317), including "yield problems" (PTX334), and failure of SB's sonication method (PTX316).

These factors collectively caused SB to seek an extension of the Option Period (TX2324). In January 1977, Huygelen told Takahashi that, notwithstanding these problems, SB needed only a three or four month extension (PTX315). A month later, however, Huygelen wrote to Brown of SB that "new difficulties were encountered a few days ago with Osaka strain" and, as a result, the "best estimate now for beginning of clinical evaluation is now mid-summer and completion end of year" (PTX317), which required more than a three or four month extension.

***28** Thus, in April 1977 SB requested and received a ten-month extension of the Option Agreement (PTX324). The Option Period was extended from June 1, 1977 to March 31, 1978. SB had to inform Biken if it desired a license by December 31, 1977, and any licensing agreement had to be finalized by June 30, 1978. Ten months was the length of the extension SB sought (PTX324), and Huygelen believed SB could make a decision by the end of 1977, the new deadline (PTX320). There is no persuasive evidence to support SB's argument that ten months was thought at the time to be insufficient.

2. Initial Merck Contacts with Biken

During the initial two-year period of the Agreement, SB was aware that Merck had approached Biken about receiving the Oka strain. In early May 1976, Dr. Maurice Hilleman of Merck had spoken with Takahashi at a conference in Atlantic City, NJ, and thereafter had written to Dr. Yoshiami Okuno, Takahashi's superior, expressing interest in the Oka strain (TX1002). In a telex of May 24, 1976, Ray Kutsunai, SB's Japanese representative, reported that Takahashi "has turned down Dr. Hillman's [sic] request for strain" (TX2192). [FN12] In July 1976, Dr Boyd Woodruff of Merck visited Takahashi and Okuno and learned that Biken has entered into an exclusive agreement with SB and that Merck would be unable to obtain a sample of the Oka strain (TX1005). They discussed aspects of Takahashi's vaccine published in the literature and Woodruff was given three unpublished papers.

FN12. Merck argues that this statement is hearsay; because I ultimately find for Merck, I do not reach a decision on this objection.

SB also learned of this meeting--in August 1976, Kutsunai of SB reported that "Dr. Woodruff of Merck personally called on Dr. Takahashi and made a strong pitch for their strain" (TX2199). There is no persuasive evidence that SB viewed the contacts between Takahashi and Merck as not permitted under the Option Agreement. Likewise, there is also no persuasive evidence that any of the information conveyed by Takahashi to Woodruff was confidential and no evidence that the unpublished papers contained any information that had not been published elsewhere in some level of detail.

Following that meeting, Woodruff wrote to Okuno, noting "I am disappointed that it will not be possible to study your vaccine in the Merck, Sharp & Dohme Research Laboratories, however, we understand the reasons that the attenuated virus cannot be released at this time" (PTX312). There is no evidence that Merck knew of Biken's specific obligations under the Option Agreement. Neither Woodruff nor any other Merck representative ever saw a copy of the Agreement (Tr. 145).

C. April 1977 to June 1978: Additional Delays Leading To A Second Extension Of The Option Agreement

1. The Second Extension

After receiving the ten-month extension, SB

encountered additional problems. Huygelen wrote that the Oka strain was "more difficult than other strains with regard to virus release from cells" (PTX328), that "we encountered problems in releasing the virus from the cells" (PTX364) and "this resulted in new delays of a few months" (id.). Another SB memo refers to "last minute problems in the testing of the diploid cells" (PTX331). On December 20, 1977, eleven days before the extended deadline for advising Biken whether it wanted a license, Brown wrote to Biken requesting an additional three-month extension (PTX336).

***29** On January 12, 1978, in response to SB's request, Biken sent a proposed amendment to the Option Agreement granting the extension but on the condition that, if SB did not take a license, it could not manufacture any varicella vaccine for three years (PTX340). Clinton H. Brown of SB reported that "Osaka will approve extension but on conditions I consider unsatisfactory" (PTX342). In another memo he noted that the conditions imposed by Biken "suggest that Osaka has lost patience with our test program" (PTX343).

As of March 1978, another extension of the Option Agreement had not been agreed to and Brown traveled to Osaka (PTX347). He learned that Biken was very unhappy with SB (id.). In a memorandum summarizing the meeting, Brown wrote that Biken "had been shocked to learn that SB was working on a strain [of varicella virus] of its own" and that Takahashi "felt SB had deceived him" (id.). Although SB had received the Oka strain from Biken, it continued to develop another strain (Tr. 1638). An SB document indicates that Kutsunai of SB had advised Huygelen not to mention to Takahashi that SB was working on other varicella strains (Brown dep. 6/3/98 at 41).

Ultimately, Biken learned of SB's potentially competing endeavors. Biken's ensuing belief that it had been deceived by SB was, as Brown noted, "a serious problem" (PTX347) involving "a serious situation and something not at all desirable for SB, especially in this country where reputations play such an important role and are quickly spread" (PTX347). Following further negotiations, Biken agreed to delete the provision to which SB objected (PTX350). Then, however, SB proposed an extension of nine months (rather than the three months it had earlier requested) in consideration for "a modest amount" (PTX349), but Brown subsequently reported that the Biken board "was quite displeased with recent events" and he recommended signing the amended three-month extension that Biken was willing to accept (PTX355).

On April 24, 1978, SB signed the amendment, which extended the Option Period to June 30, 1978 (PTX357). In the forwarding letter, SB provided notice of its desire to receive a license, retroactive to March 31, 1978 (id.). The signed amendment reflected Biken's intention to put a limit on the on-going negotiations, expressly providing that the Foundation "shall not agree to further extension of the term of the AGREEMENT for any reason whatsoever," (PTX357 Item 3), and requiring that SB provide Biken with a written explanation of why it had become necessary to extend the Option Period twice (PTX357 Item 2). Under this extension, the Option Period was extended to June 30, 1978, and the period for concluding a license agreement was extended to September 30, 1978 (PTX357). If a licensing agreement was not concluded by that time, the Option Agreement terminated by its terms (PTX306, Art. 4). SB was aware that it was required to finalize a license agreement by September 30, 1978 (PTX361). Brown's memo of his March 1978 meeting with Biken also noted:

> ***30** Dr. Kawamata seemed to keep focusing the discussion on the USA, and while I did not mention anything about it I am concerned lest SB's general indifference towards vaccines in the USA prove to be another source of misunderstanding in the future.

(PTX347).

In May 1978, John Chappell, a Vice President of SB, visited Biken. In an apparent attempt to address Biken's interest in development of a vaccine for the United States, he asserted in a follow-up letter that while "we are not very active in the U.S. market at the moment, we do have the capability to mount clinical trial, and secure product registrations" and in support of that statement said, "SB's Rubella vaccine is registered and marketed in the US" (PTX361).

The record, however, reflects that Chappell's statement was untrue. SB has withdrawn its rubella vaccine from the United States market in 1976--two years earlier (Huygelen 11/4/98 dep. at 12). Thus,

in contrast to Chappell's statement to Biken that "SB's Rubella vaccine is ... marketed in the US," SB was reporting to the FDA that SB "has not marketed Cendevax [rubella] in the United States since late 1976" (PTX445). Rubella was the only vaccine SB had ever sold in the United States (Huygelen 11/4/98 dep. at 12), and SB did not again market a vaccine in the United States until the late 1980's (id. at 13-14).

2. Contacts Between Merck and Biken

After Woodruff's visit in July 1976, there were no further contacts between Biken and Merck until April 15, 1977, when Hilleman wrote to Okuno stating:

> I am writing to inquire how things are coming along. Do you still have your relationship with another company or is there any possibility that the matter can be reopened? We continue to be most desirable of some sort of arrangement with you, if that is possible. Could you please let me know.

(PTX322).

Okuno responded:

> Our Foundation is still within the period of Option Agreement with another company. His program seems working not so well as expected, and we have not received a definite answer from him but must have it within this year. If a satisfactory agreement is not established with him, I wish to have some sort of arrangement with you.

(PTX323).

In reply, Hilleman requested that Okuno let Merck know "if your current correspondent ceases to display interest so that we can initiate talks with you" (TX1009).

Merck next contacted Takahashi and Okuno in September 1977 when Woodruff and Edgar H. Philbrick, Jr. visited to determine "if the option had expired" (TX1012). At that meeting, they learned that SB's option was scheduled to expire in March 1978 (id.). During the course of that meeting, Woodruff was asked whether the existence of the Option Agreement required Biken to enter into a license agreement. Woodruff accurately responded that it "usually did not" (id.). Following the meeting, Philbrick wrote to Okuno stating:

> [Merck was] pleased to learn that the option, under which your varicella strain is being studied, will expire in March. At that time if there are no further contractual obligations, we would be very interested in discussing this matter with you again. (PTX329).

***31** Around this time Biken also received an inquiry from Sclavo Institute concerning the Oka strain (PTX330). Therefore, Biken was aware of growing commercial interest in its Oka strain and wanted SB to move promptly toward a decision and to finalize a license agreement.

The next contact occurred in December 1977 when Hilleman wrote to Okuno saying:

> It is nearing year's end and I would wish to express our continued interest in your and Dr. Takahashi's chicken pox vaccine. Are things at the point which we could discuss them at this time? (PTX335).

On January 5, 1978, Okuno informed Hilleman of the three-month extension SB had requested (PTX339) and Hilleman again deferred discussion (PTX341). In early February 1978, Dr. Martin F. Malkin and Tatsuo Asada of Merck visited Okuno and Takahashi "to reconfirm Merck's interest in evaluating the vaccine" (TX1016). Malkin was told that REDACTED there is no evidence such information was confidential or that its disclosure caused any harm to SB.

On March 30, 1978, a Mr. Tsuji of Biken advised Malkin of SB's three-month extension and Malkin, in turn, reported that to Hilleman (TX1017). On June 13, 1978, Woodruff met with Takahashi "to reinforce prior statements of interest in his varicella vaccine" (TX1021). During the meeting, Woodruff was shown a letter apparently describing the clinical trial of Dr. Max Just on SB's vaccine--a study that Dr. Francis E. Andre of SB characterized as a "simple trial" involving only twenty people (Andre dep. at 24). The only specific information that Woodruff reported receiving was that REDACTED (TX1020).

In addition, Just presented the complete results of his clinical investigations publicly in Berne, Switzerland sometime prior to August 7, 1978 (PTX370, Huygelen 11/4/98 dep. at 120), and again at an SB symposium in Belgium in November 1978 (Huygelen 11/4/98 dep. at 119, Huygelen 12/15/98 dep. at 91). Takahashi told Woodruff that the

results of Just's trial were about to be presented at a vaccine meeting (TX1021), which indicates that the information was not particularly secret. Takahashi also told Woodruff that REDACTED SB's contention that the information was extremely sensitive (SB Br. at 67) is supported only by testimony relating to different informationREDACTED (Andre dep. at 145). There is no persuasive evidence that this general statement on REDACTED made by Takahashi in 1978 involved extremely sensitive information.

Woodruff was also told that "to meet minimal titer needs" REDACTED (TX1021). There also is no persuasive evidence such information was confidential. Huygelen of SB admitted that "the titer of the vaccine used is information you would expect to be exchanged among the investigators" (Huygelen 12/15/98 dep. at 89-90). The conclusion that such information was not, in fact, confidential is further supported by testimony related to a document found in SB's files concerning information on the titer of Merck's vaccine (PTX300). SB's own witness testified that such information "we would also feel could be released without any problem or hesitation for our vaccine" (Andre dep. at 163). In any event, assuming that this information would have fallen under Biken's confidentiality obligation under the Agreement, that obligation ended on June 30, 1978, when the Option Period ended.

***32** During the meeting with Takahaski, Woodruff was told that SB's agreement with Biken ran until the end of September. Woodruff told Takahashi that he would visit him again in October, following expiration of the Option Agreement (TX1021). As reflected above, Merck timed its approaches to Takahashi to coincide with what it understood to be the expiration of the Option Agreement, and was careful to inquire if Biken was in a position to discuss licensing with Merck. SB also complains that in June 1978 Hilleman received "Biken's actual method for producing an Oka strain varicella vaccine" (SB Br. at 32). Takahashi had sent the information to Dr. Anne A. Gershon, a clinical investigator, who in turn sent it to Dr. C. Henry Kempe, another investigator, who, unsolicited, sent it to Hilleman (PTX 363). There is no persuasive evidence, however, that Merck sought such information.

D. June 1978 to December 1978: The Option Agreement Expires

1. Expiration of the Agreement

In March 1978, when agreement was reached on the second extension of the Option Agreement, Brown had proposed that an earlier letter he submitted to Biken be viewed "as a framework" for a license (PTX347). As indicated in a later document, Biken sent a "draft of the formal license agreement on July 26, 1978" (PTX457). There is no evidence SB responded to that draft.

An SB document of June 15, 1978 had recommended that SB "stall further, allow clinical studies currently being conducted to be completed, as well as several small scale ... surveys in major markets to be conducted" (PTX366). That recommendation may have reflected SB management's view that "varicella/zoster ... vaccine [is] of relatively low commercial interest," (PTX313), as well as REDACTED (id.).

In early September 1978, Biken sent another draft licensing agreement to SB which provided for a license only in the United States, Belgium, England, and France (TX2252). On September 18, 1978, Brown wrote to Dr. Junichi Kawamata of Biken stating:

> [I]t will be difficult if not impossible to conclude final signing by September 30, the date called for in the Option Agreement itself. You and we will probably need several more weeks in this regard. We would regard this as an extension of the negotiating period rather than of the option period which, as you know, we in effect fulfilled via my notification to you of April 24, 1978. We trust you are understanding and agreeable to this request.

(PTX373) (emphasis in original). Thus, SB expressly disclaimed seeking an extension of the Option Period, even though several obligations in the Option Agreement expressly were tied to it. There is no document from Biken agreeing to this proposal.

On September 28, 1978, a Mr. Ueda of SB reported that Tsuji of Biken stated that Biken would "continue negotiation for aiming conclusion of license agreement although Option Period expires on Sept. 30" (PTX375). [FN13] Tsuji's statement

indicated only that Biken agreed to continue negotiating, notwithstanding the expiration of the Agreement. The same document noted that Biken "showed great dissatisfaction on Huygelen's explanation on present development status and future plan for clinical study" (id.). Since no license agreement was finalized by September 30, 1978, the Option Agreement expired by its terms.

> FN13. SB argues that this document constitutes inadmissible hearsay. For three reasons I find that the document is admissible. First, it is an admission by a party-opponent and therefore is not hearsay, under Rule of Evidence 801(d)(2), as Ueda was an employee of SB. Second, it falls under the "ancient document" exception to the hearsay rule (Rule 803(16)), as it has been in existence for over 20 years. Third, it falls under the "business records" exception (Rule 803(6)), as it is a "memorandum" "made at or near the time by" "a person with knowledge" and "kept in the course of a regularly conducted business activity."

*33 While SB claims otherwise, the evidence shows that both SB and Biken understood that the Option Agreement had expired--or more precisely, that there was no legally binding relationship in effect. For example, a 1979 memo by Huygelen recited that "our Option Agreement with the Foundation in Osaka has expired" (PTX446). In addition, Brown of SB, who had written to Biken proposing an extension of the "negotiating period," admitted that "there was not an extension of the negotiating period" (Brown dep. at 225-26).

While it may have continued cordial discussions with SB, Biken also understood that the agreement had expired as of September 30, 1978, as reflected in the December 1978 Biken board minutes referring to "the no-agreement state" with SB (PTX393) and the minutes of the subsequent February meeting which note "[t]he validity of our Option Agreement with [SB] has expired and we are under no agreement officially" (PTX403). Put simply, I do not view Biken's on-going negotiations and apparent resistance to cutting off all discussions with SB as any indication that an enforceable contractual agreement requiring the two entities to continue their business relationship existed after September 30, 1978.

2. Contacts by Merck with Biken

In October 1978, Woodruff and Asada again met with Takahashi. Woodruff was told that the Option Agreement had expired (PTX378), which further confirms Biken's understanding of its contractual obligations. Takahashi told Woodruff that SB had decided to REDACTED in the production of the varicella vaccine (PTX379). There is no persuasive evidence such information was confidential, and the evidence establishes that it was not. One SB witness testified that REDACTED as not something that SB wanted to keep secret (Andre dep. at 122), while another SB witness admitted that all vaccine manufacturers, at that time REDACTED (Huygelen 11/4/98 dep. at 63-64). Huygelen also stated in a letter to Takahashi that "[r]esearchers all over the world are REDACTED for the production of killed and live vaccines" (TX1623). Moreover, SB's REDACTED had been reported to the World Health Organization (TX2264) and to clinical investigators such as Dr. Stanley A. Plotkin of the Children's Hospital of Philadelphia (PTX388). [FN14] There is no evidence that SB's REDACTED was confidential.

> FN14. SB argues that this document, a letter written by Andre, an SB employee, constitutes inadmissible quintuple(!) hearsay. I do not need to rely on this document to make my decision in this case, but in any event, I also find that the document is admissible. First, at least two layers of the hearsay are stripped away because an admission by a party-opponent is not hearsay under Rule of Evidence 801(d)(2); Andre was an employee of SB and Plotkin regularly performed work for SB as a clinical researcher, even if not a full-time employee. Second, it falls under the "ancient document" exception to the hearsay rule (Rule 803(16)), as it has been in existence for over 20 years. Third, it falls under the "business records" exception (Rule 803(6)), as it is a "memorandum" "made at or near the time by" "a person with knowledge" and "kept in the course of a regularly conducted business activity."

In any event, information concerning SB's REDACTED and the improved effects caused by REDACTED was provided to Biken in November 1978 (TX2263). The Option Agreement previously had expired on September 30, 1978, and the confidentiality obligations of Biken had expired three months earlier, at the end of the Option Period.

Woodruff also was informed that SB still was having difficulty making a REDACTED vaccine (PTX379). There is no evidence such general information was confidential. Woodruff also discussed with Takahashi how Merck should submit a proposal to obtain release of the Oka strain from Biken (id.). Following that meeting, Woodruff--having been told that the Option Period had expired--reported to Hilleman that "the time is right for Merck to make a proposal ..." (id.).

***34** On November 10, 1978, Mary McDonald of Merck sent a letter expressing Merck's "firm interest in conducting an evaluation of your varicella vaccine with a view toward determining its medical and market potential" (PTX386). Woodruff separately informed Kawamata and Takahashi that Merck was "prepared to sign an agreement containing time limitations" (TX1029). At a meeting on December 13, 1978, the Biken board reviewed the status of negotiations with SB (PTX393). The minutes mention SB's REDACTED and note that "we decided to watch the progress in the no-agreement state" (PTX393). The minutes also noted that a proposal had been received from Merck (id.). These facts confirm that, despite Merck's dogged interest in obtaining the rights to the Oka strain, SB's potential ability to secure a license was still very much alive at this point.

On December 26, 1978, Kawamata responded to Merck's letter stating:

> As may be you are already informed, we are carrying on negotiations concerning our varicella vaccine with another company; I regret, therefore, that I cannot negotiate with you at present on confidential disclosure agreement.

(PTX395). Biken's decision to continue to deal exclusively with SB presumably was based on SB finally having shown progress in its work with the vaccine. On December 21, 1978, Huygelen had given Kawamata an update on SB's work, which stated that an Investigational New Drug application ("IND") had been filed on December 15 and that "our first clinical trial is expected to start now very soon in the Philadelphia area by Dr. S. Plotkin" (TX1630). The letter also reported that SB expected soon to begin three other clinical trials as well (id.).

E. January to May 1979: Merck Obtains Information from Plotkin and Learns that Biken Expects to Conclude a License Agreement

1. Contacts with Plotkin

Plotkin, of the Children's Hospital of Philadelphia, conducted clinical trials with the varicella vaccines of Biken, SB, and Merck (TX2347, TX2412). Plotkin was one of only a few United States clinical investigators interested in varicella vaccine (Andre dep. at 48-49). In late November 1978, SB met with Plotkin to discuss clinical testing of SB's vaccine (PTX388). At that meeting SB learned from Plotkin, that:

> Merck has its own strain of varicella vaccine and is accelerating its program. Data exist for healthy children but not immunosuppressed children. (Id.).

As of that time, Plotkin already had committed to doing a comparative study of Biken's Oka strain vaccine and Merck's KMcC strain vaccine (PTX390), which refutes SB's assertion that Hilleman arranged for the comparative study only after learning that Plotkin would be testing SB's vaccine (SB Br. at 33). Under the Option Agreement Biken was allowed to use its vaccine in clinical trials, and SB knew Biken was working with several United States investigators, including Plotkin, and had provided them with vaccine samples and information (PTX381, PTX384). Nothing in the Option Agreement precluded United States studies by Biken, and there is no evidence that SB, which knew of such studies, believed Biken was precluded from conducting them.

***35** In February 1979, Merck's Hilleman learned that Plotkin, without Merck's consent, had substituted SB's vaccine for Biken's, and had written to Plotkin stating:

> The agreements made with you in the discussion of 11/16/78 (see attached) were that you would be testing our KMcC strain vaccine and Oka strain vaccine prepared in Japan by the Biken Institute as stated in your November 16 protocol.
>
> In our discussion you advised me that the Biken produced vaccine was recently stated by BoB to be unsatisfactory because of Mycoplasma contamination. You stated further that because of this, you substituted a lot of vaccine produced by SB that was represented to have been made using the same seed strain. You did say that your research committee did approve the substitution. You also stated that to your best knowledge the varicella vaccine made at SB had never been used

in people, or at least in children, to date.
We are very concerned about this substitution and our concern may be expressed as follows:
(a) We were not advised or consulted about the substitution.
(b) The SB vaccine was not approved by us.
(c) We knew nothing about the preparation or testing of the SB vaccine. We had confidence with the Biken-produced vaccine since it had had very extensive prior use in man in Japan.
(d) The vaccine was given in the community where Dr. Wiebel works using Dr. Wiebel's contacts and with a consent form that bears both Dr. Arbeter and Dr. Wiebel's signature.
Our feeling is that the truth of the situation was not revealed in the conduct of the trial and this could prove troublesome if any untoward effects result from use of that vaccine.
Because of these circumstances, we ask that you send to us promptly:
(a) The release protocol for the SB lot of vaccine covering those aspects that relate to safety and potency.
(b) A sample of the SB vaccine so that we can test it for viral infectivity and particle count.

(PTX401). Dr. Robert E. Weibel of Children's Hospital complied with Hilleman's request (TX1044).

Merck had a legitimate reason to seek the release protocol for SB's vaccine relating to safety and potency as well as a sample of the SB vaccine to obtain information on viral infectivity and particle count, and there is no evidence to suggest that Merck had any other reason. There is no evidence that Plotkin was precluded in any way from providing the information and sample to Merck. Plotkin had signed no confidentiality agreement with SB (Andre dep. at 43-45), and SB never had discussed confidentiality obligations with Plotkin or any other clinical investigator (id. at 44, 46). Moreover, even if the information Plotkin provided could in some way be viewed as covered by the Option Agreement (then expired), a disclosure by Plotkin would be a breach by SB since Plotkin, under Article 5, paragraph 3 of the Option Agreement, was an "other party furnished by SB with the Strain," and SB was responsible for any disclosure by him (PTX306).

***36** SB offered no persuasive evidence that the specific safety data that Plotkin sent to Hilleman was at the time confidential. The documents contained no indication of confidentiality on their face. An SB witness testified that safety data sent to clinical investigators is "in the public domain" and not confidential (Huygelen dep. at 101). Andre also testified that information of the type found it SB's files concerning Merck's vaccine--which included titer, dose, storage, and use information (PTX300)--was not confidential as to either Merck's or SB's vaccine (Andre dep. at 62, 162-63). SB also offered no evidence that the vaccine sample used in the comparative study was at the time confidential. Andre of SB testified:

> I was not concerned because I didn't--the only concern I had was the fact that he was proposing the [comparative] study. I mean, everybody knew around that time what was in our vaccine, because it had been presented at meetings, and so there was no information that I felt would help Merck that had been passed to them.

(Andre dep. at 58-59).

2. SB Similarly Obtained Information from Clinical Investigators About Merck's Vaccine

On September 3, 1979, Huygelen forwarded to Takahashi information he had received concerning Merck's vaccine, including that it contained 800 pfu per dose, that Merck's vaccine was not freeze-dried, that Plotkin had no major clinical reactions with Merck's vaccine, and that Gershon had indicated that one of the two normal seronegative adults that she had inoculated developed varicella (TX2311). Huygelen specifically requested that Takahashi "keep this information strictly confidential" (TX2311).

In February 1980, SB received from Dr. Allan M. Arbeter, an associate of Plotkin, a copy of a contractual proposal submitted to NIAD (TX2347), which included a discussion of the varicella vaccine trials already conducted by Dr. Stuart E. Starr, Arbeter, and Plotkin using Biken's vaccine, SB's vaccine, and Merck's vaccine (TX2347), as well as the detailed results of clinical trials of Merck's KMcC vaccine (TX2347).

3. Merck Learned that Biken Expected to Enter a License Agreement with SB

As of February 1979, the Biken Board of Directors believed that a license agreement with SB

would soon be finalized (PTX403), and in March, Biken sent SB a revised draft agreement (PTX401). On April 25, Brown sent Kawamata a revised proposal (PTX415). In other words, even at this late date and despite all of the allegedly "inequitable" acts SB attempts to ascribe to Merck, those acts seemed to have no affect on Biken's Board's willingness to enter into a license with SB.

In March 1979 Woodruff called Takahashi based on his understanding of the expiration of a "3-Month 'No-Negotiation' Period (Ended in Mid Feb)" (PTX407). He was told that SB had obtained good test results in Switzerland, had improved the yield and purity of its vaccine by REDACTED that Kawamata was moving closer to continuing with SB, and that Merck's chances "[were] almost nil" (TX1050).

***37** SB has offered no persuasive evidence that the general information concerning improved yield as a result of REDACTED was confidential. In any event, any confidentiality obligations of Biken had ended on June 30, 1978, when the Option Period ended.

Believing that the Agreement between Biken and SB had expired, McDonald of Merck (who had written to Kawamata in November 1978) suggested that a final effort be made to "discourage [Biken] from 're-entering' into a relationship with [SB] and to encourage them to cooperate with Merck" and that "[Biken should] be presented with the reasons for choosing Merck over [SB], e.g., greater research and marketing expertise, etc." (TX1052). Woodruff and Asada, therefore, met in April with Kawamata and Tsuji and again learned that SB and Biken were close to agreement (PTX413). They were informed that, within the technical staff of Biken, there was "dissatisfaction with the progress of [SB]" but that the Biken directors were "fearful that cancellation of the contract by Osaka University based on poor performance, would result in prolonged legal problems, possibly even a law suit which would be very detrimental to the image of the Institute" (id.).

In a follow up letter of May 1, 1979, from Woodruff to Kawamata, Merck again expressed its interest in Biken's Oka strain if "it becomes necessary for you to separate from your existing contractual arrangement" (PTX416). There were no other contacts between Merck and Biken for the next six months. At that time, Merck expected to proceed with its own KMcC vaccine, which had performed satisfactorily--achieving a 100% seroconversion rate, but also causing some minor reactions (TX1060, TX1061).

F. June to November 1979: Deterioration of the SB/Biken Relationship

1. SB Fails to Sign a License Agreement

As of June 1979, nearly nine months had passed since Brown's letter requesting an extension of the negotiating period of "several weeks," and nearly two years had passed since the original deadline for concluding a licensing agreement; however, no licensing agreement had been reached between Biken and SB. Reflecting Biken's growing impatience, Kawamata sent SB a letter on June 8, 1979, stating:

> Enclosed, please find our final license agreement draft in duplicate to respond to your recent letter of April 25, 1979, in which your agreement draft was also enclosed.
>
> Whether this is acceptable to you or not, we must regretfully state that this would be our final agreement reviewing all of our past discussions, your comments in the letter as well as your draft sent to us.
>
> Because there are a number of other parties showing their interest in our varicella vaccines, we are being forced to set a deadline on this matter so that you may please indicate within ten (10) days of your receipt as to whether you can accept or decline this agreement.

(PTX418). SB understood that Biken was offering its final proposal: "the letter here was clear. He said it was the final agreement." (Huygelen 11/4/98 dep. at 146). The final draft agreement offered by Biken offered exclusive rights in most European and North and South American countries and non-exclusive rights in many countries (PTX423).

***38** Notwithstanding the express ten-day deadline, Biken had not received a response from SB as of July 21, 1979 (PTX425). By the end of September 1979, SB still had not replied to Biken. Huygelen wrote to Kawamata indicating that Brown "had not had the time yet to rewrite the Varicella agreement" (PTX433). A week later, Brown of SB acknowledged that Biken was unhappy with SB's failure to respond (PTX434, PTX438).

These documents refute SB's assertion that "Biken was not negotiating in good faith" (SB Br. at 14, 22) (emphasis in original). SB has offered no persuasive evidence or plausible reason why Biken would not have wanted to reach an agreement on a license.

2. SB's Development Problems

By the fall of 1979 Biken became unhappy with SB's continued failure to make a satisfactory vaccine more than four years after the signing of the Option Agreement.

REDACTED

In a letter of October 23, 1979, Takahashi reported to Plotkin that Biken had tested SB's vaccine, that it was not satisfactory, and that "I and [the] Board of our Foundation are seriously anxious about the manufacturing of Oka strain vaccine [in SB]" (PTX437).

SB was fully aware of Biken's unhappiness. An internal SB memorandum in October 1979 reported that:

REDACTED

> They are unhappy about trials with this material enough so if they proceed a license may be denied ... Ray [Kutsanai] concerned about [SB's] reputation in the face of what is perceived as [SB's] inability to produce and/or to do what they say they will do.

(PTX438).

On October 22, Kutsanai, SB's representative in Japan, attended a meeting requested by Kawamata. His memo describes the meeting:

> They were all cordial at first but as we exchanged our usual greetings, one could sense that something was brewing. They were trying to find the right timing to bring out the bad news.
> Dr. Kawamata started off by saying that it was unfortunate that SB was taking so long to produce an effective varicella vaccine.

REDACTED

> A mention was also made that the agreement draft discussion cannot be continued in the same spirit in which it was started.

(PTX443).

Kutsunai's memo also described a telephone conversation with Takahashi on October 31: "His attitude at that time was very cold and he clearly stated that no relationship existed any more between [SB] and Biken," and that Takahashi "did not want [SB] to have anything to do with the Oka strain." (id.). A later SB telex described the situation as "very grim" (PTX439). On November 2, 1979, Kutsunai again met with Drs. Kawamata, Kubo, Takahashi, and Tsuji, and his memo recording that meeting stated:

REDACTED

> ... After they had spoken their minds, attempt was made to explain to them that the multiple center won't be starting until January or February 1980 and fortunately a new batch of vaccine will become available in December. Their reply to that was they doubted whether the vaccine can be made available for use in such a short time. The vaccine will have to go through various tests and the testing itself will take almost 2 months to complete. They were unwilling to accept my word that a usable supply of vaccine will be made available by [SB] by the time the multicenter study is ready to commence.

***39** (PTX443).

There is no evidence that Takahashi or any director of Biken had any motive to speak against SB other than unhappiness with SB's development work and concern that SB would hurt the reputation of the Oka strain (PTX443). Neither Biken nor Takahashi had incentive to favor Merck or to criticize SB unfairly. To the contrary, the logical inference is that to expedite commercialization of its vaccine Biken would have preferred that SB succeed, rather than have another company, such as Merck, start anew with the Oka strain.

For these reasons, SB's assertion that Takahashi was engaged in a "conspiracy" with Merck to undermine SB is unsupported and implausible. [FN15] SB also knew, as Huygelen reported on November 9 in a memo to A.J. Dalby, the SB executive responsible for international markets, that:

> FN15. In its reply brief SB admits that the favorable initial results of Plotkin's second clinical trial were

> not received by SB or Biken until January 1980 (SB Reply Br. at 30). SB suggested in its opening brief that Biken and Merck knew of such results in the fall of 1979 (SB Br. at 36-37).

> [O]ur option agreement with the Foundation in Osaka has expired and the license agreement has not been signed yet. This puts us in a difficult situation because of all the time and effort spent on the project.

(PTX446).

At its October 1979 meeting, the Biken Board of Directors discussed "[w]hether to cancel the [Option] agreement or not?" (TX1690). On November 19, 1979, the Biken Board of Directors decided "[a]s to the contract situation with [SB], over a year has passed and if left like this it could affect the credibility of the Oka strain so we have decided that we will notify them of our intention to cancel the option agreement" (PTX451).

3. Merck Initiates Additional Contacts with Biken

After Woodruff's letter of May 1, 1979, to Kawamata, there were no contacts between Biken and Merck for the next six months. On November 2, 1979, upon learning that SB's vaccine was doing poorly in United States clinical trials, Hilleman asked Woodruff to contact Takahashi to see whether "a door has been opened" (PTX441). Woodruff contacted Takahashi on November 12, 1979, and on November 15 sent a letter to Kawamata, again expressing Merck's interest and requesting a meeting to discuss it (PTX450).

The record reflects that at least initially, Merck did not seek to exclude SB's participation with the Oka strain, but only to be allowed to participate as well--Woodruff's November 15, 1979 letter to Kawamata stated that "the difficulties encountered in producing satisfactory varicella vaccine may offer possibility for more than one company to share in commercial production of vaccine in-various areas of the world" (id.).

4. The Alleged False Statement by Woodruff

On November 27, Kawamata agreed to meet with Woodruff. Woodruff then wrote to Takahashi:

> I have since been in touch with Dr. Hilleman and have learned more details of the clinical trials with various vaccine preparations which have been completed in the United States. With these facts available I believed I should again present to the Research Foundation for Microbial Diseases management the advantages of participation by the Merck Sharp and Dohme Research Laboratories in additional clinical evaluations, if there is to be any real hope of developing a major market position for the vaccine quickly in America. As you know, SKF has essentially withdrawn from vaccine research and marketing ....
>
> ***40** I believe the meeting to be extremely important to the future of the research with the vaccine in America. Our company has become by far the dominant commercial organization in vaccine research and development in the United States. I have confidence that our participation as a non-exclusive licensee would greatly advance the study of your vaccine, as well as the eventual extension of experimental approaches to the normal population.

(PTX453). In a meeting with Kawamata and Takahashi on December 5, 1979, Woodruff reported that they again discussed the fact that SB had "essentially withdrawn from vaccine research and marketing" as giving justification for Biken "to withdraw from [SB] for the U.S. market" (PTX454).

Woodruff's statement was based on a confidential report by Henri Lipmanowicz, a senior Merck employee, who had conducted a high level review of the vaccine business at the direction of Merck's chairman PTX426, tr. 160-61, 165. The report excluded SB from the companies that "remain in the U.S. vaccines market" (PTX426), and expressly noted that "two companies have recently abandoned the field (Dow and SB)" (PTX426). A 1976 SB document confirms that "Dow has essentially collapsed its vaccine business, and is no longer selling or producing" (PTX311). It was reported separately to Woodruff that SB "discontinued sale of their rubella vaccine in the United States in February 1977" (PTX456), a significant fact since "the U.S. market is quickest to adopt new pediatric vaccines" (id.).

As of 1979, SB had, in fact, largely abandoned the United States vaccine market--it was selling no vaccine in the United States and in 1976 had withdrawn from the market the only vaccine (rubella) it had ever sold in the United States

(PTX405); (Huygelen 11/4/98 dep. at 12). SB's own documents from that period confirmed its limited interest in vaccines, especially in the United States, saying:

REDACTED

(PTX313); and "I am concerned lest SB's general indifference toward vaccines in the U.S.A. prove to be another source of misunderstanding [with Biken] in the future" (PTX347).

The statement by Woodruff, which in context concerned the United States market and was qualified by the word "essentially," was based on an internal Merck report and was consistent with SB's own documents. During the period of the Option Agreement, SB had a limited interest in vaccines, especially in the United States (PTX311, PTX313, PTX319, PTX347), and SB knew that its absence from the United States market was a point Merck legitimately could argue to Biken (Huygelen dep. at 57).

5. The Termination Letter

On December 18, 1979, the Biken Board reviewed and approved a letter prepared since the November Board meeting canceling the Option Agreement (PTX566). On December 20, 1979, Biken sent the letter to SB stating:

> [W]e hereby terminate, as of the date of this letter, the said Option Agreement (including the said Memorandum) for the following reason:
> ***41** Since we sent you our draft of the formal license agreement on July 26, 1978, the negotiations have been carried on between both parties relating to the terms and conditions of such license agreement, but any final agreement relating thereto has not yet been reached. Accordingly, a 'more formal agreement' as specified in Article 4 of the Option Agreement is not concluded within 6 months after the end of the Option period extended under the Memorandum, namely June 30, 1978.

(PTX457). Although Biken terminated its exclusive dealings with SB on December 20, 1979, the December Biken Board minutes contain no reference to Merck or to Woodruff's statement concerning SB.

The Option Agreement had expired as of September 30, 1978. Biken's letter of December 20 expressly referred to that in the last sentence quoted above. That letter, therefore, should be construed fairly as an effort to eliminate any uncertainty in light of the subsequent dealings of the parties and to clarify the termination of the relationship.

G. January 1980 to February 1982: Biken Negotiates License Agreements with SB

In a memo of January 7, 1980, Brown of SB acknowledged that "Handai-Biken's termination is within their rights--indeed we have been at their mercy ever since the second extension of the original (June 1, 1975) Option Agreement expired in '78." (PTX461). His memo indicated that Kutsunai would be contacting Biken to see "whether the door is firmly shut." (id.).

On January 30, 1980 SB received preliminary results of Plotkin's second clinical trial of SB's vaccine, which were positive (TX2343). On January 30, 1980 SB sent two letters: the first letter advised Takahashi on SB's progress with its vaccine (TX1720). The second letter from Brown to Kawamata stated SB's continued interest in a licensing agreement (TX2346). On March 1, 1980, SB met with Biken and learned that "the way is open to proceed with negotiations on both varicella and mumps." (PTX465).

Biken immediately began negotiations with Merck. SB knew the details of those negotiations (PTX479, PTX480). Biken also continued to negotiate a licensing agreement with SB and in May 1980 SB was offered non-exclusive rights in the United States, Belgium, and Switzerland (PTX472), with an understanding that Biken would "consider adding further territories when [SB] has successfully produced vaccine" (PTX473). SB rejected Biken's offer of such rights (PTX472) and requested that "such a limited agreement not be submitted to the Osaka board for approval" (PTX470) (emphasis in original).

At that time, SB and Biken were negotiating license agreements for both varicella and mumps vaccines. Biken was willing to offer SB non-exclusive worldwide rights to its mumps strain (PTX475). In June 1980, SB decided to proceed with the mumps negotiations, but to do so "independently from varicella because we would like to think it over again especially in view of large

initial payment in relation to small market potential for varicella" (PTX476). By July 1, 1980, Kutsunai advised Huygelen that SB "will proceed with mumps letter of intent [with Biken] but will not discuss varicella" (PTX477).

***42** In November 1980, Merck and Biken entered into a licensing agreement giving Merck non-exclusive rights to the Oka strain and Biken know-how in the United States and Canada (PTX551). On April 1, 1981, D.E. Boultbee of SB wrote to Brown that "I want mumps signed and sealed before approaching [Biken] about varicella again" (PTX486). On June 23, 1981, Biken offered Institu Merieux a non-exclusive license for "the countries of European Community except Belgium, on equal terms with that of Merck & Co." (PTX490).

On November 10, 1981, Biken offered SB non-exclusive varicella rights (TX2400). SB understood that it was receiving "exactly the same conditions" as were offered to Institut Merieux (id.). On February 18, 1982, SB and Biken entered into a licensing agreement giving SB non-exclusive rights to the Oka strain and Biken know-how in the countries of Europe (PTX552).

IV. CONCLUSIONS OF LAW

A. Certain of SB's Claims are Barred by the Statute of Limitations and Laches

Claims for intentional interference with contract or prospective business relations are subject to the three-year statute of limitations of 10 Del. C. § 8106; Williams v. Caruso, D. Del. 966 F.Supp. 287, 293 (1997). Although statutes of limitations do not directly apply, equity follows the law and, in appropriate circumstances, applies the statute of limitations by analogy, denying relief when claims are brought after the analogous statutory period. See In re Dean Witter Partnership Litig., Del. Ch., C.A. No. 14816, 1998 Del. Ch. LEXIS 133 at *11-12, (July 17, 1998).

In addition, "where the statute bars the legal remedy, it shall bar the equitable remedy in analogous cases or in reference to the same subject matter." Kahn v. Seaboard Corp., Del. Ch., 625 A.2d 269, 272 (1993); see also United States Cellular Inv. Co. v. Bell Atlantic Mobile Sys., Inc., Del.Supr., 677 A.2d 497, 502 (1996). Thus, SB's claim for unjust enrichment likewise is subject to a three-year bar.

The statute begins to run at the time of the alleged wrongful act "even if the plaintiff is ignorant of the cause of action." In re Dean Witter, 1998 Del. Ch. LEXIS 133 at *15. SB's counterclaims, first asserted in June 1998, involve matters that occurred between 1976 and 1979. Accordingly, SB's counterclaims are barred absent some basis for tolling. SB has the burden of showing a basis for tolling of the statute. See, e.g., Playtex, Inc. v. Columbia Cas., Del.Super., C.A. No. 88C-MR-233, 1993 Del.Super. LEXIS 286 at *10, Del Pesco, J. (Sept. 20, 1993). Under Delaware law, tolling applies only in very limited circumstances--where the injuries were inherently unknowable, see, e.g., Pack & Process, Inc. v. Celotex Corp., Del.Super. 503 A.2d 646, 651 (1985), or where there has been fraudulent concealment, see, e.g., Playtex, 1993 Del.Super. LEXIS 286 at *9. Even when tolled, the statute of limitations is suspended only until a plaintiff discovers his rights or, by exercising reasonable diligence, should have discovered such rights. See In re Dean Witter, 1998 Del. Ch. LEXIS 133 at *21.

***43** SB argues that its claims are not barred "because Merck's tortious and inequitable actions have been concealed until unearthed during discovery in this litigation" (SB Br. at 73), and because SB did not know of Merck's conduct (SB Br. at 74). However, concealment is not enough to toll the statute–there must be fraudulent concealment, which requires "that something affirmative be done by a defendant, some 'actual artifice' which prevents a plaintiff from gaining knowledge of the facts, or some misrepresentation which is intended to put the plaintiff off the trail of inquiry." Halpern v. Barran, Del. Ch., 313 A.2d 139, 143 (1973) (citations omitted). The three instances of supposed concealment alleged by SB fall far short of fraudulent concealment and do not otherwise establish a basis for tolling the statute.

SB first complains that Takahashi told SB in 1976 that he had turned down Merck's request for the Oka strain and that there was not the "slightest possibility" that he would give the Oka strain to Merck (SB Br. at 73). Takahashi's statement cannot reasonably be termed a concealment since there is no evidence that, at the time, he harbored a secret

intent to give the strain to Merck. Accepting, arguendo, that Takahashi actually made that statement (which is hearsay), it is indisputable that in 1976 (and all the way through 1979) Merck was unable to obtain the Oka strain from Biken. Moreover, SB knew, at least by 1980, that Merck in fact had obtained a license and had received the strain. Thus, any "concealment" ended 18 years before SB filed its counterclaims. [FN16]

> FN16. In its reply brief SB says that the fact Merck obtained the strain in 1980 "does not mean SB had any reason to know about the continual meeting between Merck and Biken during the time the Option Agreement remained effective " (SB Reply Br. 48-49) (emphasis in original). SB's contention is wrong for two reasons. First, if the basis for tolling is the supposed statement that Biken would not give the strain to Merck, once that fact is no longer "concealed," any basis for tolling ends. Second, SB's own documents show that it in fact knew Takahashi was meeting with Merck during the Option Agreement and attempting to obtain rights to the Oka strain.

SB next complains that Takahashi asked Woodruff to conceal their conversations from Takahashi's supervisors (SB Br. at 73). On one occasion Takahashi requested that Woodruff not attribute Takahashi's November 12, 1979 comments to him in discussions with Kawamata because Biken had not yet reached consensus on issues related to licensing of the Oka strain (Trial Tr. 154-56). There is no evidence supporting SB's assertion that Takahashi wanted to conceal his discussions with pharmaceutical companies (including Merck) from Kawamata for some nefarious reason. Indeed, SB's contention is refuted by the fact that on other occasions Takahashi, in the presence of Kawamata, met with Woodruff (TX1005, TX1012). Most importantly, SB does not allege that Takahashi was attempting to conceal information from SB. Moreover, the most that was "concealed" was a conversation related to Merck receiving a license, a fact which SB ultimately knew by 1980.

The third "concealment" of which SB complains is that "Biken continued to deny that any information was transmitted to Merck during the duration of the Option Agreement as late as the April 1998 deposition of Mr. Kamada." (SB Br. at 73). SB has not established that there were any "denials" (i.e., instances in which there was a concealment) by Biken to SB at any time from 1975 to 1998, let alone any misrepresentation. Thus, SB has pointed to nothing that constitutes fraudulent concealment such as to justify tolling of the statute of limitations.

*44 The policies underlying laches and the statute of limitations also support dismissal of SB's claims. SB essentially has presented a paper record of events occurring more than 20 years ago, from which it asks the Court to draw inferences about motive and conduct not reflected in the documents themselves. All of the critical witnesses--the Biken board members who ultimately made the decision to cease dealing exclusively with SB--are deceased, inhibiting the ability of Merck and Biken to defend against these claims.

B. Doctrine of Unclean Hands

1. Standard for Unclean Hands

Well established law dictates that "when a party who seeks relief in this Court 'has violated conscience or good faith or other equitable principles in his conduct, then the doors of the Court of Equity should be shut against him." ' E.J. Stephen, Inc. v. Ceccola, No. 7578, Del. Ch., 1984 LEXIS 596, at *5 (July 9, 1984)(citing Brodley v. Jones, Del.Supr., 59 A.2d 463 (1947)); see also Keystone Driller Co. v. General Excavator Co., 290 U.S. 240 (1933)(denying relief to an intellectual property holder due to its unclean hands); ONTI, Inc. v. Integra Bank, No. 14514, Del. Ch., 1998 WL 671263, at *3 (Aug. 25, 1998); Sherwood, Inc. v. Cottman Transmission Sys., Inc., Del. Ch., C.A. No. 6768, 1982 WL 17882, at *2 (April 15, 1982) (denying injunctive relief to plaintiff because of his unclean hands due to breach of contract). [FN17]

> FN17. As stated in Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co., 324 U.S. 806, 814 (1945): The guiding doctrine in this case is the equitable maxim that "he who comes into equity must come with clean hands." This maxim is far more than a mere banality. It is a self-imposed ordinance that closes the doors of a court of equity to one tainted with inequitableness or bad faith relative to the matter in which he seeks relief, however improper may have been the behavior of the defendant.

In fashioning a remedy for unclean hands, the Court has a wide range of discretion in refusing to aid the "unclean litigant." Monsanto Co. v. Rohm & Haas Co., 3d Circ., 456 F.2d 592, 598 (1971). The application of the doctrine of unclean hands is not "bound by formula or restrained by any limitation that tends to trammel the free and just exercise of discretion." Keystone Driller Co. v. General Excavator Co., 290 U.S. 240, 245-46 (1933). Moreover, this Court specifically has rejected a "no harm, no foul" exception to the application of this doctrine. Nakahara v. The NS 1991 Am. Trust, Del. Ch., C.A. No. 15905, 1998 LEXIS 50, at *81 (March 20, 1998). [FN18]

> FN18. "A court of equity will not use its equitable powers to condone such activity. Equity does not reward those who act inequitably, even if it can be said that no tangible injury resulted ." Id.

SB has levied a claim of unclean hands against Merck for allegedly inequitable acts that it committed on its own behalf. SB also has levied a claim of unclean hands against Biken for certain acts which SB argues should bar any claim which Biken could bring against SB. As Biken's exclusive licensee in the United States and pursuant to a separate contract with Biken, Merck has asserted that it has standing to sue SB for trade secret misappropriation. In order for Merck to have standing to sue in its own name, well established law dictates that Merck's exclusive license with Biken must constitute an assignment. See Waterman v. McKenzie, 138 U.S. 252, 255 (1891); Minco, Inc. v. Combustion Eng'g, Inc., Fed. Circ., 95 F.3d 1109, 1116-17 (1996).

In this regard, Merck explicitly has argued "in terms of the right to sue for misappropriation ... [w]e, to use [SB's counsel's] words, stand in Biken's shoes as to a claim of misappropriation." (TX 1295 at 80:11-22.). Therefore, as Merck contends that as Biken's exclusive licensee in the United States, it "stands in Biken's shoes," any defenses SB has against Biken are fully applicable to Merck. See, e.g., Mid-Atlantic Equip. Corp. v. Elder, E.D. Pa., No. 95-CV 886, 1995 WL 447602, at *5 n.2 (July 25, 1995) ("As Yamaha's assignee, Mid-Atlantic 'stands in the shoes' of the assignor and assumes the assignment subject to all defects and defenses."); K.B. v. State Farm Fire and Cas. Co., Ariz.Supr., 941 P.2d 1288, 1292 (1997)(holding that "[a]n assignee steps into the shoes of her assignor" and "cannot alter the defenses or equities of the third party"). Smith v. Cumberland Group, Ltd., Pa.Super., 687 A.2d 1167, 1172 (1996) ("Where an assignment is effective, the assignee stands in the shoes of the assignor and assumes all of his rights ... [c]onversely an assignee's right against the obligor is subject to all of the limitations of the assignor's right, to all defenses thereto ... and counterclaims which would have been available against the assignor had there been no assignment ...."); Florida v. Family Bank of Hallandale, Fla. Dist. Ct.App., 667 So.2d 257, 259 (1995) ("The assignee steps into the shoes of the assignor and is subject to all equities and defenses that could have been asserted against the assignor had the assignment not been made."). [FN19]

> FN19. In fact, in earlier proceedings in this case the Court allowed the litigation to proceed without the addition of Biken as an involuntary plaintiff under Del. Ch. Ct. R. 19 only "so long as [Biken's] commitment is adequate to make sure that SmithKline is prejudiced neither in the discovery nor potentially the trial." (TX 1295 at 96:21-24)(emphasis added).

***45** Thus, at least in theory, if SB is able to establish inequitable conduct of either Merck's or Biken's part it should succeed on its claim of unclean hands against Merck. For the reasons specified below, I find the evidence simply does not establish conduct that requires the Court to reject Merck's claims against SB by operation of the doctrine of unclean hands.

2. Merck's Claims Are Not Barred by Unclean Hands

SB bears the burden of establishing that Merck has "unclean hands," see, e.g., Greco v. Columbia/ HCA Healthcare Corp., Del. Ch., 1999 Del. Ch. LEXIS 24 at *24, Strine, V.C. (Feb. 11, 1999), and must show that Merck "violated conscience or good faith or other equitable principles" in its conduct, E.J. Stephen, Inc. v. Ceccola, Del. Ch., 1984 Del. Ch. LEXIS 596 at *5, Berger, V.C. (July 9, 1984). Ultimately, the "unclean hands doctrine is aimed at providing a court of equity with a shield from the potentially entangling misdeeds of the litigants in any given case." Nakahara v. The NS 1991 Am.

Trust, Del. Ch., 718 A.2d 518, 522 (1998). Ultimately, the doctrine is about public policy, and the Court has the broad discretion to refuse relief if SB can establish that Merck does not meet a very basic though inexact standard: "where the litigant's own acts offend the very sense of equity to which he appeals." Id.

a) SB Has Failed to Establish Unclean Hands due to Tortious Interference

SB attempts to support its contention that Merck's claims are tainted by alleging three forms of inequitable conduct: 1) that Merck induced Biken to breach the Option Agreement by, among other things, frustrating negotiations with SB; 2) that Merck improperly obtained confidential material and information from clinical researchers and through Takahashi; and 3) that Woodruff fraudulently misrepresented SB's vaccine business. These are the same allegations that formed the basis for SB's claim for tortious interference. SB has been unable to establish that Merck tortiously interfered with SB's existing or prospective contractual relationship with Biken. Thus, SB's unclean hands claim must also fail on this point.

To establish tortious interference with either an existing contract or prospective contractual relation, a party must demonstrate (1) the existence of a contract or a prospective contractual relationship (2) about which the accused party knew and (3) an intentional act that is a significant factor in causing a breach of that contract or termination of that prospective contractual relationship (4) absent a justification for the interference and (5) causing damages to the party whose contract was breached or whose relationship was disrupted. See CPM Indus., Inc v. Fayda Chems. & Minerals, Inc., Del. Ch., C.A. No. 15996, Jacobs, V.C. (Nov 26, 1997), Mem. Op. at 18-19.

(1)Contractual Relationship and Knowledge

As far as the first two requirements are concerned, the Option Agreement was a contract between Biken and SB, and Merck knew at least generally of its existence. However, insofar as SB claims that Merck induced a breach of Biken's confidentiality obligation, there is no evidence that Merck knew of that provision, let alone its scope. Neither Woodruff nor any other Merck employee saw a copy of the Option Agreement, and there is no evidence that Merck was aware of its specific terms.

***46** Insofar as SB complains that it did not receive a "worldwide exclusive license" (see, e.g., SB Br. at 1), SB never had a contract right to such a license, either before or after expiration of the Option Agreement. The Agreement itself conferred no right to a license per se, but only the right to evaluate the Oka strain and thereafter attempt to negotiate a license. And even assuming Biken agreed to extend the negotiating period as SB claims, SB continued to have only some expectation of a license. Even then, its expectancy interest was less than a worldwide exclusive license because Biken only offered SB limited exclusive rights in some areas. Thus, SB at most had an expectancy interest in a limited license and not a contract right to one. In addition, any such expectancy interest was terminable at will by either party. Assuming that these details do not totally preclude SB from making its claim, my analysis continues.

(2)Intentional Act, Proximate Cause, and Damages

The third requirement has two parts: an intentional act and evidence that the act was a significant factor, i.e., the proximate cause of the claimed damage. [FN20] As mentioned above, SB has identified three actions that purportedly caused it to be damaged: 1) that Merck induced Biken to breach the Option Agreement; 2) that Merck improperly obtained confidential material and information from clinical researchers and through Takahashi; and 3) that Woodruff fraudulently misrepresented SB's vaccine business. As outlined below, SB has failed to prove any induced breach of any implied or explicit term of the Option Agreement by Merck.

> FN20. I am sensitive to the fact that while there may be numerous "significant" causes in a tortious interference action in the colloquial sense of the word "significant." To make sense of the tort, the Court chooses to examine whether or not the acts of which SB currently complains can be fairly viewed together or individually as the proximate cause(s) of the alleged damage.

(i) SB Has Failed to Establish that Merck Induced Biken to Breach the Option Agreement

Generally, the language of a contract must be given its ordinary meaning and, "[a]bsent ambiguity, the parties' intent must be determined by reference to the express terms of the Agreement." Cincinnati SMSA Ltd. Partnership v. Cincinnat. Bell Cellular Sys. Co., Del. Ch., C.A. No. 15388, 1997, Del. Ch. LEXIS 109 at *17, (Aug. 13, 1997), aff'd, Del.Supr., 708 A.2d 989 (1997). Where the language of the agreement "is plain and clear on its face, i.e., its language conveys an unmistakable meaning, the writing itself is the sole source for gaining an understanding of intent." City Investing Co. Liquidating Trust v. Continental Cas. Co., Del.Supr., 624 A.2d 1191, 1198 (1993)(citing Citadel Holding Corp. v. Roven, Del.Super., 603 A.2d 818, 822 (1992)). The "language of an agreement ... is not rendered ambiguous simply because the parties in litigation differ concerning its meaning." Id. In addition, when the words of a contract are not subject to different interpretations and when the words do not otherwise create ambiguity when viewed in the light of other contractual provisions, this Court "will not consider extrinsic evidence to interpret the meaning of the agreement." Cincinnati SMSA, 1997 Del. Ch. LEXIS at *15.

***47** The Option Agreement did not prohibit communications between Merck and Biken. The only limit imposed by the Option Agreement on Biken's dealings with other prospective licensees was that Biken agreed "not to give such option or any license for manufacture, sale or use of a varicella vaccine made from their Strain to any third party during the option period as specified in Article 3 and for three months thereafter" (PTX306, Art. 1, ¶ 2). Article 1, paragraph 2 imposed no limit on Biken's ability to communicate or negotiate with third parties at any time during the term of the Option Agreement. SB's claim that "Biken could no negotiate with anyone else" (SB Br. at 1) is directly contradicted by the unambiguous language of the agreement.

Although the unambiguous language of the agreement precludes consideration of extrinsic evidence, SB's claim also is unsupported by any such evidence. No testimony from any Biken or SB employee involved in the negotiation of the Option Agreement suggests that the parties understood Biken to be limited in the way SB claims. Similarly, no document relating to the negotiations of the Option Agreement suggests any such limit on Biken's ability to talk or to negotiate with others.

The contemporaneous conduct also refutes SB's claim that Biken was precluded from speaking to other potentially interested parties. As noted, SB was fully aware that Takahashi met with representatives of Merck during the period of the Option Agreement on the subject of Merck's interest in the Oka strain. There is no evidence that SB viewed such meetings as prohibited by the Option Agreement.

SB's reliance on the testimony of Yoshio Kamada regarding his interpretation of the contract restrictions on Biken's ability to meet with Merck is misplaced. Kamada had no involvement in negotiation of the Option Agreement (Kamada dep. at 33-34), no involvement in discussions concerning its meaning (id.), and, as SB concedes, no personal knowledge concerning any aspect of the Option Agreement (id. at 33-35, SB Br. at 5 n. 4). In addition, SB's attempt, in a Rule 30(b)(6) deposition, to inquire into the contentions of Merck as to the meaning and legal effect of the parties' rights under the Option Agreement was improper. See, e.g., Teigel Mfg. Co. v. Globe-Union, Inc., D. Del., C.A. No. 84-483, Stapleton, J. (Oct. 5, 1984), Oral Ruling at 14 ("[A] lay person shouldn't be required to formulate a party's contention in response to deposition questioning."). Moreover, such testimony cannot contradict the plain language of the agreement.

SB's reliance on Kawamata's letter stating "I cannot negotiate with you at present" cannot be used to modify the language of the agreement. Moreover, in that letter Kawamata expressly declined negotiating with Merck prior to 1980, and there was never any exchange of licensing proposals between Merck and Biken before that time. In any event, even if Biken and SB had "understood" that Biken could not negotiate with others, the various meetings between Woodruff and Takahashi and other communications in which Merck expressed its interest in the Oka strain did not constitute "negotiations." In fact, Merck did not authorize negotiations with Biken until April 1980 (PTX467). Thus, Merck did not induce Biken to breach any provision of the Agreement by engaging Biken agents in these discussions during the effective period of the Agreement.

(ii) SB Has Established a Breach of the Option Agreement's Confidentiality Provision.

***48** Biken's confidentiality obligations under the Agreement are contained in Article 5, paragraph 4. The specific language is as follows:

> The Foundation also agrees during the option period and during the term of any License Agreement executed pursuant thereto not to disclose the Strain and information and data relating thereto, including any data, strains, or information provided by [SB], to any third party except to enable the Foundation to conduct research testing in the field, to publish or release the same to scientific and/or academic institutions, and to deposit a limited quantity of its own Strain to ATCC, U.S.A., or other accredited depositories for the purpose of facilitating the Foundation's patent applications. (B13).

(PTX306). By its terms, the limit on disclosure by Biken applied only "during the option period and during the term of any license agreement executed pursuant thereto ..." (PTX306, Art. 5, ¶ 4). Because no license agreement was ever executed, the confidentiality obligation ultimately applied only "during the Option Period" which ended June 30, 1978. There is no persuasive evidence that the "Option Period" ever was extended beyond that date.

Biken and SB clearly separated the Option Period and the negotiating period and clearly limited Biken's confidentiality obligations to the Option Period. A court may not disregard unambiguous language of a contract, even if it views such language as unreasonable. See Daniel D. Rappa, Inc. v. Englehardt, Del.Supr., 256 A.2d 744 (1969); Ramsey v. Department of Natural Resources and Envtl. Control, Del.Super., C.A. No. 96A-03-001, 1997 Del.Super. LEXIS 143 at *9, Terry, J. (Mar. 20, 1997).

There is nothing unreasonable, however, about the express language of the Agreement. Because SB was required under the terms of the Agreement to begin negotiations for a license three months prior to the expiration of the Option Period and finalize such license within three months following the expiration of the Option Period, Biken sensibly could have concluded that it wanted to be able, once the Option Period had expired and if no licensing agreement had been reached, to actively begin eliciting the interests of other parties--which could require disclosure (under appropriate confidentiality provisions) of the strain and related information to such parties.

SB's argument (SB Reply Br. at 43 n.31) that the Court may imply an additional obligation is incorrect where, as here, the parties expressly and unambiguously specified when Biken's confidentiality obligation ended. Cincinnati SMSA, 1997 Del. Ch. LEXIS 109 at *22 ("When the express terms of the contract do not suggest the omission of such an obligation and the implied obligation sought to be enforced conflicts with the express terms, the Court will not supply a term allegedly omitted."). For these reasons, insofar as SB complains about disclosures after June 30, 1978, any such disclosures did not violate the Option Agreement. [FN21]

> FN21. The June 30, 1978 cut-off date for Biken's non-disclosure obligations also applies to any argument that SB might have that related to non-Biken clinical researchers (e.g., Dr. Plotkin) who SB argues potentially could be viewed as constrained by Biken's non-disclosure commitment. In any event, there is no evidence that Plotkin or any of SB's clinical investigators violated a confidentiality obligation to SB by providing information to Merck. SB admits that its clinical investigators did not sign confidentiality agreements (Andre dep. at 118). Although SB claims there was a "general practice in the industry" (SB Br. at 72) concerning confidentiality by investigators, the testimony provides no real basis for that statement nor is there any other persuasive evidence that could act as a legal hook for the claim that there was a contractual or quasi-contractual obligation in this particular case. Andre admitted that his only experience was in Europe (Andre dep. at 5, 9-10), that he had no personal knowledge of what the general practice was in the United States (id. at 41, 45), that until he dealt with Dr. Plotkin he had never been involved in clinical trials in the United States (id. at 41), that he knew of no agreement that Plotkin had signed (id. at 43), and that he had never had any discussion with Plotkin or any other clinical investigator about confidentiality obligations (id. at 44, 46). Moreover, SB received from Plotkin information about Merck's KMcC vaccine, received from Gershon information on her tests of Merck's vaccines, and forwarded such information to

> Takahashi with a request that it be kept "strictly confidential" (PTX430). SB later received the detailed clinical results of Plotkin's studies of the Merck vaccine (TX2347). SB cannot reasonably complain that Merck's receipt of such information was improper, but that SB's was not.

***49** SB, however, has pointed to disclosures which occurred before June 30, 1978. SB claims that these allegedly impermissible disclosures--which were made by Takahashi--amount to a breach of Biken's confidentiality obligations under the Agreement. SB goes on to argue that if Biken is tainted by a breach of contract, that breach must be imputed to Merck and must operate to foreclose the misappropriation claims that Merck asserts in this litigation as Biken's assignee. [FN22]

> FN22. In response to SB's argument Merck argues that 1) the non-disclosure provision did not apply to Takahashi and 2) the provision only applies to the Foundation and not to its officers and employees. Both of these arguments, while immaterial, are ridiculous. First, while Takahashi may have been technically employed by the Institute (i.e., his paycheck came from the Institute) he clearly operated as an agent of the Foundation (Kamada dep. at 194; Ichikawa dep. at 23). Moreover, Merck's own witness recognized that the distinction between the Institute and the Foundation was a fiction (TX1021). Second, if the non-disclosure provision in the Agreement did not apply to the officers and employees of the Foundation, then to whom did it apply? Merck's reading of the non-disclosure agreement is simply inappropriate as it would force the Court to accept an implausible interpretation of the provision.

Pursuant to the Option Agreement, Biken explicitly agreed to a clear prohibition on the disclosure of information. Despite that fact, it seems that Takahashi shared certain protected information with Merck. For instance, Biken provided Merck with information on its own clinical trials related to the Strain. Biken informed Merck that REDACTED (TX1016, TX1016-2, TX1016-3).

On June 13, 1978, Merck and Biken met yet again. At this meeting, Takahashi showed Woodruff a letter describing the clinical trial results of Just, an SB consultant who was evaluating SB's Oka strain varicella vaccine in Europe (TX1021, TX1021-6, Tr. 47, TX1598, TX1599, Woodruff dep. at 101-04). As testified by Merck's Hilleman, this information was valuable as it represented the first clinical trial with the Oka strain performed in a Western country with a Caucasian population with different antigens:

> Q. And you wanted to see how the Biken strain would do against your own strain?
> A. Yeah. I need to know is that Biken strain going to be horrendously virulent, for instance, in Caucasians? It is going to be immunogenic in Caucasians? You have two completely different distributions for HLA antigens.

(Hilleman dep. at 42.)

The prior Japanese clinical trial data was not detailed sufficiently to permit a commercial manufacturer to determine if the vaccine was safe and effective. For this reason, such information was relevant to understanding the viability of developing the Oka strain into a vaccine for world-wide use (Huygelen dep. at 28-29).

At the June 13th meeting, Takahashi also provided Woodruff with information regarding the titer of SB's vaccine, the yields of varicella vaccine obtained through SB's production process, and additional information regarding the results of Biken's clinical trials (Woodruff Tr. at 47-49, TX1021, TX1021-7).

As mentioned above, Takahashi's sharing with Merck the detailed results of Biken's continuing clinical trials in Japan, unpublished papers, SB's clinical trial data, the yields obtained through SB's process, and other information regarding the Oka strain violated Biken's explicit obligation not to disclose such information under Article 5.4 of the Option Agreement (TX1533). While I have found that, as a matter of fact, some of this information cannot be viewed fairly as confidential, that determination does not change the legal conclusion that Biken breached the Agreement's non-disclosure provisions. Biken's non-disclosure obligations prior to June 30, 1978, clearly precluded the exchange of this sort of information.

***50** Merck unsuccessfully tries to fit itself under the scientific/academic exclusion provided in Article 5.4. Woodruff testified in his capacity as a 30(b)(6) witness and at trial that Takahashi treated him the same way he treated clinical investigators (Woodruff

dep. at 133; tr. 59-60). Likewise, at trial, Woodruff testified that:

> Well it certainly was clear that I was receiving information that was developed at RIT as well as information that was developed in Takahashi's area. What we were having were the typical open kind of discussions that you have when you go visit a researcher, who talks about what he has done, what other people have done who are working with his material.

(Tr. 174.)

Woodruff's trial testimony is truly extraordinary as it concedes that Biken violated both the text and the underlying rationale of Article 5.4 of the Option Agreement. Although Article 5 .4 did allow Biken to disclose information in certain narrow circumstances to enable Biken to conduct research in the field or to deposit the Oka strain in a depository, Merck's Woodruff did not fall within these exceptions. (TX1533).

Woodruff claimed that he was justified in receiving such information because he worked for Merck Research Laboratories and was not a commercial individual (tr. 93). This justification is simply not credible. Woodruff did not visit Biken for scientific curiosity but for the very specific commercial purpose of obtaining a sample of the Oka strain so that Merck could commercially develop the strain into a varicella vaccine. As provided by the agreement, Biken simply should not have provided to Merck any non-public data and information it generated related to the strain or any information and data that Biken received from SB. Thus, the fact that Takahashi disclosed such information was a violation of the Option Agreement.

Even if Biken did breach its non-disclosure obligation there is no indication that this breach was "induced" by Merck. While Merck may have been a happy recipient of information from Takahashi, I am unpersuaded that during the effective time of Biken's non-disclosure obligations Merck in any way coerced or improperly encouraged Takahashi to divulge information. As described in detail above, the evidence gathered at trial shows that, despite contractual limitations and alleged "general practices" of confidentiality in the industry, prior to the development of commercial manufacturing processes a significant amount of information about different companies' research initiatives and developments flowed somewhat freely between and among the companies. This flow came through academic clinical researchers as well as through company-sponsored scientists.

As mentioned, however, even if Merck's conduct would not merit the application of the unclean hands doctrine to Merck, Biken's conduct could transitively affect Merck as Merck is prosecuting Biken's claims. Thus, the question is whether Biken's breach of its non-disclosure obligation is so offensive that, as a matter of public policy, the Court should turn a deaf ear to the misappropriation of trade secrets claim. I find that Biken's breach of contract does not merit the application of the unclean hands doctrine.

***51** First, unlike Merck's trade secrets claims where there were discrete confidential pieces of information that SB misappropriated, there is little or no persuasive evidence that the vast majority of information Merck received from Biken while Biken was limited by its non-disclosure obligations was confidential. As detailed in my findings of fact above, most of the information was either not confidential, was not detailed, or, even if confidential, was shortly released to the public domain. Of course, those facts do not relieve Biken of its confidentiality obligation, but at the same time they certainly limit the repugnancy of the breach.

Second, and most importantly, Takahashi's disclosure amounts to a simple breach of contract. Breach of contract, alone, does not necessarily require the application of the unclean hands doctrine. Our courts have recognized, even if only by implication, that in appropriate circumstances breach of contract is justified and efficient. See E.I. DuPont de Nemours & Co. v. Pressman, Del.Supr., 679 A.2d 436, 445 (1995); see generally, Richard Craswell, Contract Remedies, Renegotiation, and the Theory of Efficient Breach, 61 S. Cal. L.Rev. 629 (1988). Of course there may be situations where, in the process of breaching a contract, a party acts so inequitably that the doctrine of unclean hands must apply. This is simply not that case. After closely examining the particular circumstances involved, the Court is unconvinced that as a matter of public policy Biken's actions were so offensive that the Court should not endeavor to address Merck's claims. [FN23]

FN23. At least in theory, though the doctrine of unclean hands is of no help to SB, it is not as if my legal conclusion would leave similarly situated litigants without a remedy. SB could have brought a breach of contract claim against Biken for damages. Of course, because of the statute of limitations and laches, SB could not now assert that claim. Biken's breach, of which SB was on notice more than 20 years ago, is well past ripeness for adjudication.

Thus, even to the extent that SB has demonstrated that there was a breach of contract on Biken's part on the issue of disclosure, there is insufficient evidence that Merck or Biken acted inequitably to establish that either entity's actions "transgressed equitable standards of conduct" in any way that might justify the application of the unclean hands doctrine. Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co., 324 U.S. 806, 815 (1945). To hold otherwise would yield an absurd result. If every breach of contract automatically evoked the unclean hands doctrine, then any non-breaching party to a breached contract would have the effective ability to act inequitably against the breaching party with impunity (even as late as 20 years after the breach). Any future complaint by the breaching party would be barred by the doctrine of unclean hands. This is not a sound rule of law, and I refuse to recognize such a policy.

(iii) No Proximate Causation or Damages

As mentioned, tortious interference also requires a showing that the alleged interference proximately caused a breach of the contract or termination of the prospective contractual relationship and resulting damage. CPM Indus. at 18-19. Merck's conduct prior to June 1979 was not the cause of any damage that SB currently claims, i.e., SB's loss of its claimed expectancy interest in an exclusive worldwide license. Simply put, on June 8, 1979, Biken proposed to SB a licensing agreement that included exclusive rights in most European and North and South American countries (including the United States) and non-exclusive rights elsewhere (PTX418). This proposal was accompanied by a letter stating that it was Biken's final proposal (id.). SB failed to accept Biken's offer. Thus, the only significant and proximate cause of SB's failure to secure a license for itself was SB's independent decision to reject Biken's offer.

*52 The only conduct of Merck after June 1979--Woodruff's statement about SB withdrawing from vaccine marketing and research in the United States--did not cause Biken to end its relationship with SB, as discussed below. Moreover, in April 1980, SB also refused to accept a non-exclusive license that included rights in the United States.

b) Justification for Any Interference

Another necessary element for a claim of tortious interference is the absence of justification for the alleged interference. CPM Indus. at 18-19. As a competitor, Merck was justified in seeking from Biken a license for the Oka strain, even if that resulted in SB receiving a more limited license or even no license at all. Bowl-Mor Co. v. Brunswick Corp., Del. Ch., 297 A.2d 61, 64 (1972). "[O]ne is privileged purposely to cause a third person not to enter into or continue a business relationship with a competitor of the actor" if the relation concerns a matter involved in the competition and improper means are not used. DeBonaventura v. Nationwide Mut. Ins. Co., Del. Ch., 419 A.2d 942, 947 (1980).

In determining whether a competitor used wrongful means to interfere with another's prospective contractual relations, the factors set forth in Section 767 of the Restatement (Second) of Torts are considered. See, e.g., Shearin v. E.F. Hutton Group, Inc., Del. Ch., 652 A.2d 578, 589-90 (1994). These factors are: the nature of the actor's conduct; the actor's motive; the interests of the other with which the actor's conduct interferes; the interests sought to be advanced by the actor; the social interests in protecting the freedom of action of the actor and the contractual interests of the other; the proximity or remoteness of the actor's conduct to the interference; and the relations between the parties.

There is no evidence that Merck engaged in improper means in seeking a license with Biken. If anything, both Merck and Biken were overly respectful of SB's rights. Merck's various contacts with Biken in which it expressed its interest were timed carefully to coincide with what it understood to be the expiration of the Agreement. And Biken declined to negotiate or to discuss licensing terms with Merck, even though there was no limit on its ability to do so. Furthermore, as detailed below,

the only arguably improper act that can be attributed to Merck--Woodruff's statements about SB's exit of the U.S. market--was not, in fact, improper.

3. SB Has Failed To Show That Merck Was Unjustly Enriched

SB's claim that Merck unjustly was enriched is based on the same three allegations of inequitable conduct, i.e., that Merck induced Biken to breach the Option Agreement, that Merck improperly obtained confidential material and information, and that Woodruff fraudulently misrepresented SB's vaccine business.

Merck did not retain unjustly any benefit to SB's detriment nor did Merck's retention of such benefit violate "the fundamental principles of justice or equity and good conscience." Cantor Fitzgerald, L.P. v. Cantor, Del. Ch., 724 A.2d 571, 585 (1998). In addition, because SB did not accept the license offered by Biken in June 1979 that included exclusive United States rights and also did not accept a later offer of non-exclusive United States rights, there was nothing "unjust" about SB's loss of such rights to Merck.

4. Woodruff's November 1979 Statement Violated No Rights of SB

*53 SB claims that Woodruff's statement in late 1979 concerning SB's withdrawal from the United States vaccine business was a fraudulent misrepresentation (SB Br. at 59). The elements that must be shown to sustain an action for fraudulent misrepresentation are a false representation of a material fact, made with knowledge of its falsity or recklessness as to whether it is true or false, with the intent of misleading another into relying on it, justifiable reliance on the misrepresentation, and resulting injury proximately caused by such reliance. See, e.g., Brzoska v. Olson, Del.Supr., 668 A.2d 1355, 1367 (1995); Hudson v. Wesley College, Inc., Del. Ch., 1998 Del. Ch. LEXIS 235 at *43, Steele, V.C. (Dec. 23, 1998). SB has failed to establish any of these elements.

a) There Was No Knowing Misstatement

Even if Woodruff's statement could be construed as inaccurate, there is no evidence that Woodruff believed it to be inaccurate. Fraudulent misrepresentation requires that the person "must have knowledge of the falsity of his representation." Brzoska, 668 A .2d at 1367. A representation that is believed to state the truth but, because of careless expression, is misleading cannot constitute fraudulent misrepresentation. Restatement (Second) of Torts § 528. Woodruff based his statement on information contained in a high-level Merck document on which he reasonably believed he could rely, and there is no evidence that Woodruff though his statement was inaccurate in any respect.

b) Biken Did Not Rely on Woodruff's Statement

In any event, there is no evidence that Biken actually relied on Woodruff's statement, and three separate facts strongly indicate it did not. First, well before Woodruff's statement, Biken was extremely unhappy with SB's lack of progress and its failure to sign a licensing agreement. In October 1979, the Biken board was considering whether to cancel its exclusive dealings with SB. On November 19, 1979, the Biken board decided to cancel the relationship. This decision, made before the alleged Woodruff statement, conclusively demonstrates that the statement was not a factor in Biken's decision.

Second, no Biken document makes any reference to Woodruff's statement, and there is no evidence that the statement even was reported to Biken's board. And third, after Biken terminated its exclusive dealings with SB in December 1979, it continued to negotiate with SB, offering SB non-exclusive rights in the United States and other countries in 1980. In addition, Biken granted SB a license for Biken's mumps vaccine in 1980. If Biken had relied on Woodruff's statement, it would have been unwilling to offer SB any licensing rights in the United States. [FN24]

FN24. In its reply brief, SB says that Huygelen had told Biken that SB was "actively attempting" to resume rubella sales in the United States (SB Reply Br. at 35). Of course, SB never did resume its rubella sales in the United States. In any event, that reinforces the conclusion that the Biken Board did not base its decision on Woodruff's statement, since it had SB's contrary position and since it thereafter offered SB United States rights.

V. SUMMARY OF CONCLUSIONS

For the foregoing reasons, SB is enjoined from marketing its varicella vaccine in the United States or Canada for a period of three years from the date it receives approval from all regulatory agencies having appropriate jurisdiction within the United States and Canada to market its vaccine in those countries. Furthermore, judgment is entered in favor of Merck on SB's counterclaims. An Order has been entered consistent with these conclusions.

1999 WL 669354 (Del.Ch.)

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